

Structured Product Labeling (SPL) OTC Sub-team Teleconference
November 30, 2009, 1:00 – 2:00 pm ET
Call Summary

I. Call Attendees (based on emails received)

Attendance is based on email replies received. Call participants who are not listed below but were on the call (or you are listed and were not on the call) should notify Marcia Howard.

-  Paule Belony, The Belony Group LLC
-  Cheryl Blik, Teva Pharmaceuticals, Inc.
-  Richard Brandt, Quark, Inc.
-  Terry Brunone, GlaxoSmithKline
-  Gail Burke, Procter & Gamble
-  Pete Carlson, Ecolab
-  Shelia Dy Juanco, Medline Industries, Inc.
-  Chris Guay, Procter & Gamble
-  Maureen Kapustynski, Cadbury
-  Mike Koenig, FDA
-  Jeff Poisson, i4i
-  Paula Markert, GlaxoSmithKline (sub-team co-leader)
-  Alison Rago, Intagras
-  Janet Riffitts, McNeil Consumer Healthcare
-  Eva Rivera, Glemser Technologies Corporation
-  Gary Saner, Reed Technology & Information Services, Inc.
-  Jeremy Seideman, Data Conversion Laboratory, Inc.
-  Carl Strotz, Pfizer Consumer Healthcare
-  Cynthia Thompson, Kimberly-Clark Corporation
-  Craig Trautman, Intagras
-  Ranga Velagaleti, BASF Corporation
-  Karen Vescovi, Church & Dwight Co., Inc.
-  Ann Vu, FDA
-  Marcia Howard, CHPA staff (sub-team liaison)

II. Next Standing Teleconference: December 14, 2009, 1:00pm ET (unless cancelled)

III. FDA Data Council Information (*Not All-inclusive*)

- A. FDA Data Standards Council website – terminology update (November 21, 2009):
 - 1. UNII update -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml62523.htm>
 - 2. Updated terminology XML Files (include updated UNII XML file) -
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml69455.htm>
- B. FDA Data Standards Council website - update (November 12, 2009):
 - 1. Include an updated version of the SPL Starter Package with version 1.03 of the listing SPL Xforms:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml89651.htm>.
 - 2. Add a hyperlink to the HL7 SPL Working Group's SPL web page (under "Resources for You" heading):
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

IV. Upcoming SPL Educational Forums/Information (*For Your Information*)

FDA SPL R4 Training Sessions – Please visit website for updated information regarding training courses.

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucml55705.htm>

- A. **FDA Training Sessions:** Monday webinars at 10:00 am ET and Q&A sessions at 11:30 am ET (same for both; cancelled for Federal holidays)

Telephone number: 1-866-775-9435
Participant pass code: 5753366

Please dial-in early as there are a limited number of ports and when they are exhausted, no one else will be able to connect to the conferences.

To connect to the webinar, please use the following instructions:

Dates: Mondays. August 10, 2009 – December 28, 2009 (Except Federal Holidays)

Time: 10:00 – 11:00 a.m. (Eastern Time Zone)

Location: Web/Audio Conference

Web conference details:

Meeting Number: 747810891

Meeting Pass code: (This meeting does not require a password)

Join Instructions for Instant Net Conference:

1. Go to <http://www.mymeetings.com/nc/>
2. Enter the required fields.
3. Indicate that you have read the Privacy Policy.
4. Click on "Proceed".

FDA has released a series of e-Training Books and Cards that are available on the SPL Wiki page as another SPL resource to industry.

(<http://spl-work-group.wikispaces.com/>)

- B. **SPL Process Communication Forum (Process Team):** Alternating Wednesdays 1:00 - 2:30 pm ET (unless cancelled; opposite to ERDL calls)
Telephone number: 877-423-2663
PIN#: 558089
Please email Process Team co-leaders Terry Brunone (Theresa.M.Brunone@gsk.com) or Mary Beth Wilusz (mary_beth_wilusz@merck.com) if you want to get the email information.
- C. **SPL ER/DL Sub-team calls:** Alternating Wednesdays at 1:00 pm ET (unless cancelled)
Telephone number: 866-217-3840
Conference Code: 4286445422
Please email sub-team leader Michael Fahmy if you want to get the email information (michael.fahmy@bms.com).

- D. **SPL Generics Sub-team calls:** First Tuesdays of each month at 1:00 pm ET (unless cancelled)
Telephone number: 866-618-6746 (toll-free)
201-527-2133 (international/caller paid)
Access Code: 8957842
Please email sub-team leader Virginia Hogan if you want to get the email information (Virginia.Hogan@tevausa.com).
- E. **Others – *Note: although members of the various SPL sub-teams may be involved in the following programs, no endorsement or recommendation is implied***
1. CBI's Forum on [FDA's Structured Product Labeling \(SPL R4\)](#), December 8-9, 2009, in Washington, DC
 2. DIA Webinar: [Preparation of Electronic Drug Establishment Registration and Drug Product Listing \(eDRL\) Submissions in SPL format: What You Need to Know](#). (December 8, 2009)

V. Discussion Topics

- A. **SPL Content of Labeling Draft Guidance**
<http://edocket.access.gpo.gov/2009/pdf/E9-25940.pdf> (Notice)
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf> (Draft Guidance)

The SPL Leadership Team agreed to issue a letter of appreciation to FDA for their ongoing commitment to provide educational information to industry on SPL-related matters. There was no recommendation for comments to be submitted via the sub-team. Companies are encouraged to provide feedback to FDA by the requested deadline (December 28, 2009).

- B. **Import Issues**
Industry concerns regarding import issues were raised with FDA. FDA expressed its appreciation for the feedback as they want to be as helpful as possible in resolving concerns. They remain committed to training import staff and educational efforts will continue. Recognizing that both industry and FDA underwent a transition (with the June 1, 2009, deadline for OTC product e-listing), appreciation was extended to Lonnie Smith (FDA) and other agency staff for their willingness to provide assistance and training.

VI. Updates – Requesting UNII for Simethicone – see questions below

Three companies have data regarding the questions posed by FDA with respect to the UNII request for simethicone. Paula Markert (GSK, SPL OTC sub-team co-leader will send the information to the agency. Unless companies notify Marcia Howard by COB ET November 30th that they intend to submit data, it will be assumed that these companies (3) will provide responses (no responses received by November 30th deadline).

VII. Other – DeListing Procedure

There was an inquiry regarding the electronic delisting process now that companies are no longer permitted to use Excel spreadsheets. The ER/DL has a sub-group that is working on the issue. The hope is that a solution acceptable to both industry and FDA can be identified. Current recommendations include an abbreviated submission filing procedure or a “move forward” approach (*i.e.*, everything not listed by a certain date would be considered as delisted). There are pros and cons with all ideas so the ER/DL sub-group will work to resolve concerns to the best of their abilities. Marcia will keep the SPL OTC sub-team abreast of any progress. In the meantime, companies were encouraged to contact the FDA ER/DL staff to address their individual situations.

MDH/12-01-09

SPL OTC Sub-team 30 November 2009 120109.doc
Last Revised: December 1, 2009 Sent: December 1, 2009

Message received from SPL OTC sub-team member from FDA (identifying information removed):

Requesting UNII for Simethicone

You requested for one UNII to be assigned to simethicone instead of the two substances. It is the FDA Substance Registration System team's position that simethicone can always be listed as a mixture of a given type dimethicone and silicon dioxide.

Due to the amount of recent requests for assignment of a UNII for simethicone by several companies, before we can even consider the assignment a UNII to this term we have some questions.

Note that these are not to be considered as regulatory questions and are only posed as questions due to your request for the assignment of a term to be utilized in the product data elements section of a listing SPL document. You are not obligated in any way to answer these questions and should you opt to reply, your responses will not have any bearing on the approval (if applicable) or listing of your drug.

1. From some of the formulation sheets we have received with requests for an assignment of a UNII for simethicone, it appears that the potency listing is actually based on the amount of dimethicone. Do all the manufactures use a USP grade of simethicone where the amount of silicon dioxide is limited to between 4 and 7%? For example when you list 125 mg/tablet does this mean there will always be between 4 and 9 mg of silicon dioxide and 125 mg of dimethicone or does it mean 125 mg of the mixture dimethicone + silicon dioxide? If there is more than 7% silicon dioxide in a table do you list silicon dioxide as a separate ingredient?
2. What type of dimethicone is typically used? There are a variety of types of Dimethicone each of which differ by molecular weight and would get a separate UNII.
3. Which dimethicones are typically used in the manufacturing of simethicone for pharmaceutical grade material? Is this something that is always controlled? The literature indicates that dimethicones between 20 and 3000 CS are typically used. Unfortunately the USP monograph does the specify the need for the label to indicate the type of dimethicone used.
4. Do manufacturers always use the same type of dimethicone in a given product? The type of dimethicone may influence the performance of the product.